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10/530,078	04/01/2005	Mark Manasas	FIW-002.01	7458
25181	7590	06/11/2009	EXAMINER	
FOLEY HOAG, LLP			DEAK, LESLIE R	
PATENT GROUP, WORLD TRADE CENTER WEST			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,078	<b>Applicant(s)</b> MANASAS ET AL.
	<b>Examiner</b> LESLIE R. DEAK	<b>Art Unit</b> 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 December 2007.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1 and 3-41 is/are pending in the application.  
 4a) Of the above claim(s) 25-41 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,3-24 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 01 April 2005 is/are: a) accepted or b) objected to by the Examiner.  
   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
   Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-10, 15-19 and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Mitchell *et al.* (US 2001/0021835 A1; hereinafter: "Mitchell").

Regarding claims 1, 3, 4, and 19, Mitchell teaches a medical device, comprising:  
a flexible body (90), having a proximal end (12);  
a distal end (14);  
a longitudinal axis; and  
a plurality of flexible elongate members (96, 96') defined by an aperture (98, 98') extending longitudinally in the body (90), the member (96) being radially expandable with respect to the longitudinal axis;  
the device defining an eccentric lumen (24), at least a portion of the eccentric lumen (24) being offset from the longitudinal axis (see figures 10, 18 & 19, infra).

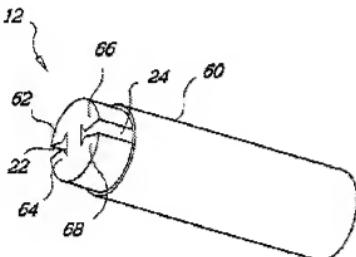


FIG. 10

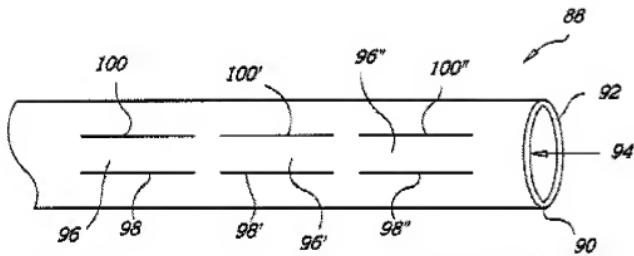


FIG. 18

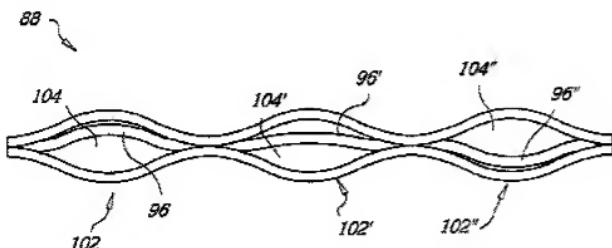


FIG. 19

When the device is expanded, it forms voids 104 within the undulating shape shown in fig. 19. The voids or lumen extend beyond the longitudinal axis of the elongate member, thereby forming a lumen that at least partly eccentric to the longitudinal axis, wherein the lattice structure of the wall provides a "perforated" lumen.

With regard to claims 5-10, the apparatus may be contracted and expanded with the use of a filament 106 or tether 112 which acts as acclaimed by applicant.

Regarding claim 6, see ¶ 0042.

Regarding claim 15, Mitchell teaches a lumen (24) formed of a flexible body member (62) attached to the device.

Regarding claims 16 and 21, Mitchell teaches that the apertures (98) near one of the ends is sealed, see fig. 18.

Regarding claim 17, Mitchell teaches that the sealed portion is openable by displacing guidewire (106).

Regarding claim 18, Mitchell teaches a helical elongate member (see fig. 22, infra).

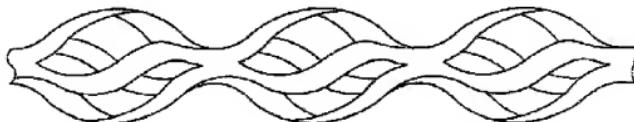


FIG. 22

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 11-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Mitchell et al.* (US 2001/0021835 A1; hereinafter: "Mitchell") in view of *Beyar et al.* (US 6,371,979 A; hereinafter "Beyar").

In the specification and figures, Mitchell discloses the apparatus substantially as claimed with the exception of a second lumen and the materials of the device.

With regard to claims 11-14, Beyar discloses a stent with multiple eccentric lumens to allow for tool and guidewire insertion. It has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See MPEP § 2144.04(VI)(B). In the instant case, it is the position of the Examiner that the addition of multiple lumens does not produce an expected result, and allows for multiple insertion points for guidewires and other tools.

Regarding claim 22, Beyar teaches multiple perforations or lumens/tubes (102) with an insert /tool (103) therein (fig. 17).

Regarding claim 23, Beyar teaches polyurethane construction (col. 4, line 16).

Claims 20, 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Mitchell et al.* (US 2001/0021835 A1; hereinafter: "Mitchell") in view of *Buscemi et al.* (US 5,464,450 A; hereinafter "Buscemi").

Buscemi teaches that radiopaque materials such as barium are desirable in stents so that they can be located within a human body. Buscemi also teaches that incorporating therapeutic materials in such devices is desirable (col. 2, lines 1-52).

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

***Response to Arguments***

Applicant's arguments filed 29 September 2008 have been fully considered but they are not persuasive. Applicant argues that the Mitchell device does not show an eccentric

lumen in the embodiment with the undulating shape. However, it is the position of the Examiner that the undulations provide lumen spaces that are eccentric to the longitudinal axis, meeting the limitations of the claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action with regard to the dependent claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
8 June 2009